

VACCINE PATENTS, MRNA TECHNOLOGY TRANSFER AND THE RIGHT TO HEALTH: REASSESSING INDIA'S INTELLECTUAL PROPERTY FRAMEWORK FOR FUTURE PANDEMICS

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ABSTRACT

The COVID-19 pandemic exposed a structural weakness in the relationship between pharmaceutical patent protection, manufacturing capacity and the right to health. India and South Africa's 2020 proposal to suspend selected obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) challenged a system in which vaccine innovation was globally valuable but production remained geographically concentrated. The debate cannot be reduced to a choice between patents and public health. Patents may support investment and rapid innovation, yet exclusive rights, trade secrets, supply contracts and national procurement policies can together restrict timely access to life-saving technologies. The mRNA experience adds a further complication: a patent waiver may remove liability for infringement without transferring the tacit know-how, process controls, regulatory data and skilled personnel required to reproduce a vaccine at scale. This article argues that India's future-pandemic framework should retain patent incentives while converting public-health safeguards from dormant exceptions into operational access architecture. The proposed framework combines a pandemic-triggered compulsory-licensing pathway, government-use powers, transparency obligations, public-funding conditions, disclosure of relevant patent and know-how information, advance manufacturing agreements, and sustained investment in regional technology-transfer

and fill-and-finish capacity. India should use its constitutional commitment to social welfare and its experience as a supplier of affordable medicines to advocate a treaty-compatible system in which access; technology transfer and innovation are designed together rather than sequenced after a crisis.

Keywords: vaccine patents; mRNA; technology transfer; right to health; TRIPS; compulsory licensing; India; pandemic preparedness

1. Introduction

Vaccines are public-health technologies whose value depends on speed, scale and broad uptake. During COVID-19, the world produced vaccines at unprecedented speed, but access was sharply unequal. By the end of 2021, approximately 10 billion doses had been produced, while only 4 per cent of people in low-income countries were fully vaccinated. The distributional failure was especially severe during the first year, when high-income and upper-middle-income countries captured most of the benefits of the new technology.¹ This was not simply a failure of scientific discovery. It was a failure to connect discovery with geographically distributed production and affordable supply.

The crisis placed intellectual property (IP) at the centre of a wider institutional problem. India and South Africa's proposal of October 2020 sought a temporary suspension of relevant TRIPS obligations for COVID-19 health technologies so that legal rights would not obstruct production and supply.² Its proponents argued that existing compulsory-licensing procedures were too fragmented and procedurally cumbersome for an emergency requiring coordinated manufacturing across jurisdictions. The proposal also reflected a concern that TRIPS had not delivered the promised diffusion of productive capacity to lower- and middle-income countries.³

¹ M. Sunder and H. Sun, "Intellectual Property and 'The Lost Year' of COVID-19 Deaths," eYLS, 2023.

² R. J. Aerts, "COVID-19 vaccines, patents and an IP waiver," *Journal of Intellectual Property Law & Practice*, 2022, doi: 10.1093/jiplp/jpac097.

³ S. Thambisetty, "The TRIPS Intellectual Property Waiver Proposal: Creating the Right Incentives in Patent Law and Politics to end the COVID-19 Pandemic," 2021. doi: 10.2139/SSRN.3851737.

The opposing position deserves serious attention. IP can help attract investment, organise technology development and reward risky research. A strong IP system was described by the American Chemical Society's patents committee as part of the incentive environment that enabled the development and deployment of mRNA vaccines.⁴ Yet the existence of an incentive does not establish that every form of exclusivity remains justified once a pandemic technology has received substantial public support, when demand exceeds the rightsholder's manufacturing capacity, or when access failures threaten life and health. The central legal question is therefore not whether patents are good or bad. It is when, how and under what conditions patent exclusivity must yield to a public-health obligation.

This article advances three propositions. First, India's patent law already contains important public-health tools, including anti-evergreening rules, compulsory licensing and export mechanisms, but legal availability is not the same as practical readiness. Second, mRNA technology shows why patents alone are an incomplete account of technology transfer: production depends on confidential process knowledge and institutional capabilities that a waiver may not disclose. Third, the right to health should guide the design and trigger of India's pandemic IP framework, not merely serve as a post hoc ethical argument. The appropriate reform is an integrated system that links patent rights to transparency, public funding, manufacturing commitments and mandatory sharing during a declared health emergency.

2. Method and analytical framework

This is a doctrinal and policy analysis of published legal and interdisciplinary scholarship on TRIPS, Indian pharmaceutical patent law, vaccine access, human rights and mRNA technology transfer. The analysis synthesises competing positions rather than treating the patent-waiver

⁴ C. C. Burton, "A strong and stable IP system incentivizes tools to combat COVID-19," C&EN Global Enterprise, 2021, doi: 10.1021/cen-09939-comment.

debate as settled. The evidence includes legal scholarship supporting a broad waiver, scholarship arguing that a waiver would be unnecessary or harmful, and work that identifies trade secrets and manufacturing capacity as distinct barriers.

The article uses the right to health as a normative interpretive lens. It does not assume that human rights automatically invalidate patent protection. The more defensible approach treats innovation and access as related public interests. A study of compulsory licensing in India characterises the debate as one between patent protection and health access but adopts a coexistence approach in which both innovation and access are legitimate interests.⁵ That approach is especially useful for pandemic law: the state must preserve incentives before a crisis while ensuring that incentives do not become an absolute claim against emergency production.

The analysis distinguishes four layers of the access problem: legal freedom to operate; access to technical information and know-how; physical manufacturing capacity; and purchasing, regulatory and distribution capacity. The distinction matters because a reform aimed at only one layer will predictably underperform. Indian scholarship has similarly concluded that access depends not only on incorporating TRIPS flexibilities into legislation, but also on manufacturing capacity and political will, with changes required in law, policy and institutions.⁶

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3. The pandemic patent bargain and the right to health

3.1 From patent incentive to public obligation

⁵ A. Ristanic, "Using Compulsory Licenses to Facilitate Access to Medicines: The Indian Experience," Lund University Publications Student Papers (Lund University), 2016, [Online]. Available: <http://lup.lub.lu.se/student-papers/record/8894039>

⁶ G. M., "Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime," 2010. doi: 10.2202/1943-3867.1061.

The patent bargain is commonly described as a temporary exchange: society grants exclusivity, and the inventor discloses an invention that will eventually enter the public domain. In pharmaceuticals, however, access depends on more than disclosure. Commercial production may require validated processes, specialised equipment, quality systems, clinical and regulatory data, supplier networks and trained personnel. The formal patent document may therefore reveal the claimed invention while leaving the practical route to safe and reliable production incomplete.

The COVID-19 experience exposed this gap between formal legal disclosure and usable technological capacity. The literature identifies vaccine nationalism, corporate concentration and the limited sharing of knowledge, data and know-how as mutually reinforcing causes of inequity. A broader account of IP nationalism argues that the major problem was not only the hoarding of finished doses but also the hoarding of knowledge protected by IP. On that account, a waiver that merely removes infringement liability may not allow a new manufacturer to reproduce an mRNA vaccine because crucial manufacturing processes are maintained as trade secrets.⁷

This does not prove that patents were the sole or even the only cause of vaccine scarcity. Infrastructure, raw materials, regulatory approval, procurement finance, export restrictions and supply-chain bottlenecks also mattered. But it does show that a legal framework focused exclusively on patent infringement is too narrow. Pandemic preparedness must ask in advance what information and capabilities a manufacturer would need to produce an approved vaccine safely, and which public or private actors can lawfully require that information to be shared.

3.2 Human rights and global vaccine inequity

International human-rights scholarship frames vaccine inequality as a conflict between private property interests and the public's interest in access to health care technologies. The post-

⁷ C. M. Ho, "Confronting Intellectual Property Nationalism," Digital Commons - DU, 2022.

COVID literature argues that existing human-rights law supplies a basis for equity but that global action remained constrained by nationalism and unequal bargaining power.⁸ A related analysis concludes that the WTO system's capacity to secure medical access is weak when profit-making corporations can maintain IP rights and when additional rules protect evergreening or test data.⁹

The right to health should not be invoked as a slogan detached from institutional design. Its practical implications include non-discrimination in access, affordability, availability of essential technologies and state responsibility to prevent avoidable barriers. During a pandemic, these implications support at least four legal consequences. States should preserve the ability to authorise production without the rightsholder's consent; public funds should carry conditions that promote downstream access; states should cooperate in transferring relevant knowledge; and emergency measures should be transparent, time-limited and subject to fair remuneration.

A human-rights approach also changes the burden of justification. The question is not whether a patent owner has a legitimate interest in remuneration. The question is whether maintaining exclusive control over a pandemic technology, in the circumstances of actual supply and need, is proportionate to the public-health harm caused by exclusion. This is a more precise inquiry than the claim that all pharmaceutical patents are incompatible with the right to health.

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4. India's existing framework: strengths and limitations

4.1 Product patents and anti-evergreening

⁸ T. A. Adekola and F. O. Majekolagbe, "Human rights law, intellectual property and vaccine nationalism: lessons for the post-COVID-19 world," *Australian Journal of Human Rights*, 2023, doi: 10.1080/1323238X.2023.2286941.

⁹ V. Nambiar, G. Kunte, and V. Bhat, "Protection of intellectual property and human rights during health emergencies: an assessment of the patent waiver proposal," *International Journal of Human Rights in Healthcare*, 2023, doi: 10.1108/ijhrh-06-2022-0064.

India's 2005 patent amendments introduced a TRIPS-compliant product-patent regime for pharmaceuticals while preserving public-health flexibilities. The literature identifies section 3(d), compulsory licensing provisions and section 107A (a)'s regulatory-experimentation exception as parts of an access-oriented design.¹⁰ Section 3(d) is particularly relevant because it raises the threshold for obtaining patents on new forms of known pharmaceutical substances, thereby limiting weak secondary patents that can extend exclusivity without a corresponding therapeutic advance. The legal literature treats the provision as an anti-evergreening measure intended to reduce the maintenance of weak patents.¹¹

These provisions remain important for future vaccines. A pandemic may produce successive formulations, variants, delivery systems and manufacturing adaptations. Patent examination must distinguish genuine technical advances from strategic layering of claims that unnecessarily delays competition. At the same time, the anti-evergreening rule should be applied with technical sensitivity: a materially improved formulation or delivery method may generate real public-health value. The objective is not to deny protection to innovation, but to ensure that additional rights correspond to additional contribution.

4.2 Compulsory licensing and government use

Indian law provides compulsory licensing as a mechanism through which a third party may produce or sell a patented product without the patent owner's consent, subject to statutory conditions and remuneration. The first Indian pharmaceutical compulsory licence, granted to Natco for Bayer's cancer medicine Nexavar in 2012, remains the principal practical example. Scholarship describes the decision as an important foundation for Indian compulsory-licensing

¹⁰ V. Asawat, "Access to Affordable Medicines in the Current Patent Regime: An Indian Perspective," 2011. doi: 10.2139/ssrn.1808605.

¹¹ J. Liu, "Compulsory Licensing and Anti-Evergreening: Interpreting the TRIPS Flexibilities in Sections 84 and 3(d) of the Indian Patents Act," Harvard International Law Journal, 2015.

jurisprudence and notes that section 92A creates a special regime for manufacture and export to countries lacking sufficient manufacturing capacity.¹²

Government-use powers offer another route. Section 100 is described in the literature as giving the Central Government a broad power to use a patent for government purposes, while section 47 reserves a narrower statutory power.¹³ In a pandemic, these powers could support procurement and emergency production, but their value depends on administrative readiness, clear remuneration rules, rapid technical assessment and coordination with regulators and manufacturers.

The limitation is operational. A compulsory licence is legally meaningful only if a capable manufacturer can use it. It must also cover, or be complemented by access to, relevant non-patent information. India's experience therefore suggests a broader lesson: compulsory licensing should not be treated as a last-minute litigation strategy. It should be embedded in a standing pandemic protocol that identifies candidate manufacturers, maps relevant patent families and establishes a rapid process for technical and regulatory support.

4.3 India's international role

India's role in the WTO waiver initiative reflected both domestic interest and global responsibility. Its large population, pharmaceutical manufacturing base and history as a source of affordable generic medicines gave it a distinctive position in global health diplomacy.¹⁴ The proposal also exposed a tension in India's policy: a country may advocate international

¹² S. Narain, "The NATCO Decision: Bringing into the Indian Patent Practice the TRIPs Flexibility of Compulsory Licensing," 2012. doi: 10.2139/SSRN.2072435.

¹³ S. K. Avasara and C. Jain, "Government Use of Patents: Understanding of Limits & Evolving Indian Jurisprudence in Comparative Light," SSRN Electronic Journal, 2019, doi: 10.2139/ssrn.3359118.

¹⁴ V. K. Chattu, B. Singh, J. Kaur, and M. Jakovljević, "COVID-19 Vaccine, TRIPS, and Global Health Diplomacy: India's Role at the WTO Platform," BioMed Research International, 2021, doi: 10.1155/2021/6658070.

flexibility while hesitating to deploy emergency tools domestically. Scholarship on compulsory licensing describes this tension as part of the debate over whether India has fully used the tools it has promoted internationally.¹⁵

Future credibility will require consistency. India should retain policy space to protect domestic access, but it should also design predictable rules that reassure innovators that emergency measures will be targeted, compensated and terminated when conditions improve. Predictability can reduce political delay while preserving the state's ability to act.

5. mRNA technology transfer: why a waiver is necessary but insufficient

The mRNA platform illustrates the difference between legal access and technological capability. An mRNA vaccine requires more than the nucleotide sequence. It requires specialised formulation, delivery systems, lipid components, process controls, quality testing, cold-chain arrangements and regulatory knowledge. The literature expressly warns that effective mRNA manufacturing involves trade-secret processes and that a waiver of liability does not, by itself, grant access to those secrets.

This point refines, rather than defeats, the case for a waiver. Patent barriers can create uncertainty and litigation risk for prospective manufacturers. The India–South Africa proposal was defended as a way to clear those barriers consistently and allow more firms to operate without fear of infringement litigation. But clearing legal risk is only the first step. A functioning transfer system must also provide know-how, personnel training, quality assurance, regulatory assistance and access to inputs.

¹⁵ C. Bhardwaj and S. Prem, “COVID-19 Vaccine: A Case of Compulsory Licensing for Social Utility!,” Social Science Research Network, 2021, doi: 10.2139/SSRN.3853761.

The WHO mRNA technology-transfer hub model is therefore best understood as institutional infrastructure rather than a substitute for patent reform. A future framework should connect legal authorisation with a network of regional hubs capable of receiving technology, adapting it to local conditions, training manufacturers and supporting regulatory approval. The hub should have authority to negotiate licences, receive publicly funded data and coordinate the transfer of confidential process information under protective conditions.

Technology transfer should also be differentiated by stage. Before a pandemic, India can support platform technology, process development and workforce training. During an emergency, it can activate a mandatory access regime for patents and know-how linked to publicly funded or strategically necessary vaccines. After the emergency, it can preserve manufacturing capacity through non-exclusive licences, regional procurement agreements and periodic exercises. This staged approach prevents preparedness from being reduced to a legal waiver announced after supply chains have already failed.

6. Reassessing the arguments against reform

The strongest objection to pandemic IP intervention is that weakened exclusivity could reduce future investment. That objection cannot be dismissed. The argument that IP contributed to rapid vaccine development is supported by the view that patent systems incentivized the underlying science and commercialisation of mRNA technologies. Any reform that makes returns unpredictable could discourage research, particularly for pathogens whose commercial markets are uncertain.

The answer is not unrestricted monopoly. It is alternative incentive design. Public procurement can reward successful development through advance purchase commitments, milestone payments, prizes, subscription contracts and guaranteed markets. Public-funding agreements can

require non-exclusive licensing or price and supply conditions when a technology is developed with substantial public support. A proposal for future pandemic preparedness similarly recommends delinking publicly funded vaccine development from monopoly rights, strengthening legal requirements to share publicly funded technologies, and investing in technology-transfer hubs and local manufacturing capacity.

A second objection is that a waiver cannot solve non-IP barriers. This is correct but incomplete. The existence of infrastructure or supply-chain problems is not a reason to preserve avoidable legal barriers. It is a reason to pair IP reform with industrial and regulatory policy. The relevant comparison is not waiver versus capacity; it is waiver plus capacity versus capacity constrained by exclusive rights and secrecy.

A third objection is that compulsory licensing may damage investment or generate diplomatic retaliation. Comparative scholarship finds that India, Brazil and Thailand have used compulsory licensing differently and that India's practice has often been connected to its generic industry rather than directly to national health emergencies.¹⁶ This suggests the need for clearer emergency criteria, not abandonment of the tool. A transparent, treaty-compatible system with fair remuneration and judicial review is more defensible than improvised action under political pressure.

7. A proposed Indian pandemic IP framework

India should adopt a five-part framework.

¹⁶ V. A. Le and M. Hyland, "Compulsory Licensing for Patented Medicines: A Comparative Legal Analysis of India, Brazil and Thailand," 2020.

First, create a pandemic access trigger. Once a competent public-health authority declares a pandemic or a comparable national emergency, the government should initiate an expedited review of patents, applications, regulatory exclusivities and relevant know-how connected to essential vaccines. The trigger should be based on health need, supply failure and manufacturing insufficiency, not on a finding that the rightsholder acted improperly.

Second, establish an emergency licensing pathway. Sections 84, 92, 92A and 100 should be integrated into a single protocol with fixed timelines, standard royalty principles, expedited hearings and coordination between the patent office, health ministry, procurement agencies and regulators. The pathway should permit domestic production and, where necessary, export to countries lacking manufacturing capacity. Section 92A's export function is particularly valuable because a pandemic cannot be solved by treating national borders as the boundary of public health.

Third, regulate public funding and public purchasing. Contracts involving substantial public funds should require disclosure of relevant patent information, reasonable supply commitments, non-discriminatory licensing during a declared emergency and transfer of necessary know-how to qualified manufacturers. Conditions should be proportionate and should protect legitimate confidential information outside the emergency purpose. The principle is supported by scholarship arguing that funders, universities and other institutions should attach downstream-access conditions to the resources they provide for pandemic technologies.¹⁷

Fourth, build a technology-transfer obligation. An emergency licence should not be limited to patent claims. Where a vaccine cannot be reproduced reliably from the patent specification alone, the competent authority should be able to require transfer of process documentation,

¹⁷ A. M. McMahon, "Intellectual Property Rights and Global Access to Health Technologies During Pandemics: Reflecting on Vaccine Nationalism, COVID-19 & the WHO Pandemic Agreement Negotiations — The Need for Collective Action and Institutional Change," *Journal of Law, Medicine & Ethics*, 2025, doi: 10.1017/jme.2025.10149.

training and validation support, subject to confidentiality safeguards and remuneration. This responds directly to the finding that trade-secret manufacturing processes can prevent a waiver from producing actual mRNA capacity.

Fifth, invest before the next crisis. India should support regional mRNA and biologics hubs, shared testing facilities, skilled personnel, domestic production of critical inputs and regulatory cooperation. The literature on India's patent system makes clear that statutory flexibilities require complementary policy and institutional capacity. Investment should therefore be treated as part of IP policy, not as a separate industrial-policy file.

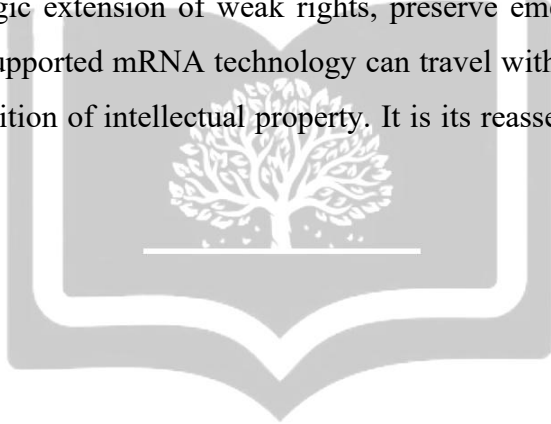
The framework should include safeguards. Emergency licences should be non-exclusive where multiple manufacturers can operate, limited to the products and period justified by the emergency, subject to fair remuneration, and reviewable by an independent body. Manufacturers should meet quality and pharmacovigilance standards. Rightsholders should receive protection against misuse of transferred information outside the authorized purpose. These safeguards preserve the legitimacy of intervention while preventing delay from becoming a substitute for due process.

8. Conclusion

COVID-19 did not establish that patents are inherently incompatible with the right to health. It established that a patent-centred system is inadequate when life-saving technologies are urgently needed across borders and when production depends on knowledge that is not fully contained in the patent document. The pandemic revealed the combined effects of vaccine nationalism, concentrated manufacturing, weak voluntary sharing and institutional dependence.

India is well placed to lead a different model. Its legal framework contains anti-evergreening principles, compulsory licensing, government-use powers and export mechanisms. Its pharmaceutical sector gives it manufacturing and diplomatic capacity. Its constitutional and public-health commitments provide a normative basis for insisting that essential technologies remain accessible. Yet these assets will matter only if they are converted into a pre-planned system with clear triggers, rapid licensing, fair remuneration, mandatory know-how transfer and sustained investment.

The central reform should therefore be conceptual as well as statutory. Pandemic IP policy must move from a narrow question—who owns the patent?—to a public-law question—what legal, technical and institutional conditions are necessary to make a safe vaccine available to those who need it? A future-proof Indian framework would answer both questions. It would reward genuine innovation, prevent strategic extension of weak rights, preserve emergency production powers and ensure that publicly supported mRNA technology can travel with the knowledge required to use it. That is not the abolition of intellectual property. It is its reassessment in light of the right to health.



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